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**TERMINAL DISCLAIMER TO OBTAIN A DOUBLE PATENTING  
REJECTION OVER A "PRIOR" PATENT**

Docket Number (Optional)  
107223.187US5

In re Application of: Anand R. Baichwal et al.

Application No.: 10/047,060

Filed: January 14, 2002

For: Controlled Release Insufflation Carrier for Medicaments

The owner\*, Penwest Pharmaceuticals Company, of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term prior patent No. 6,387,394 as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:

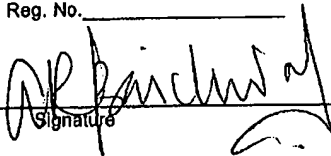
- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☒ For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☐ The undersigned is an attorney or agent of record. Reg. No. \_\_\_\_\_

  
Signature

8/18/06  
Date

Anand R. Baichwal (SVP Licensing & CSO, Penwest Pharmaceuticals Co.)

Typed or printed name

(203) 796-3732  
Telephone Number

- ☒ Terminal disclaimer fee under 37 CFR 1.20(d) included.

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

\*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).  
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

This collection of information is required by 37 CFR 1.321. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Application No.: 10/047,060

Filed: January 14, 2002

For: Controlled Release Insufflation Carrier for Medicaments

The owner\*, Penwest Pharmaceuticals Company, of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term **prior patent No. 5,612,053** as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said **prior patent** is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the **prior patent**, "as the term of said **prior patent** is presently shortened by any terminal disclaimer," in the event that said **prior patent** later:

- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☒ For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☐ The undersigned is an attorney or agent of record. Reg. No. \_\_\_\_\_

Signature

Date

Anand R. Balchwal (SVP Licensing & CSO, Penwest Pharmaceuticals Co.)

Typed or printed name

(203) 796-3732

Telephone Number

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PTO/SB/96 (12-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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**STATEMENT UNDER 37 CFR 3.73(b)**Applicant/Patent Owner: Anand R. Baichwal et al.Application No./Patent No./Control No.: 10/047,060 Filed/Issue Date: January 14, 2002Entitled: Controlled Release Insufflation Carrier For MedicamentsPenwest Pharmaceuticals Company, a Corporation

(Name of Assignee)

(Type of Assignee: corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest; or
2. ☐ an assignee of less than the entire right, title and interest  
(The extent (by percentage) of its ownership interest is \_\_\_\_\_ %)

in the patent application/patent identified above by virtue of either:

A. ☐ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or a true copy of the original assignment is attached.

OR

B. ☒ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: Anand R. Baichwal and John N. Staniforth To: Edward Mendell Co., Inc.  
The document was recorded in the United States Patent and Trademark Office at  
Reel 007543, Frame 0885, or for which a copy thereof is attached.
2. From: Edward Mendell Co., Inc. To: Penwest Pharmaceuticals Co. (change of name)  
The document was recorded in the United States Patent and Trademark Office at  
Reel 012312, Frame 0470, or for which a copy thereof is attached.
3. From: Edward Mendell Co., Inc. To: Penwest Pharmaceuticals Co. (change of name)  
The document was recorded in the United States Patent and Trademark Office at  
Reel 012315, Frame 0363, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet.

As required by 37 CFR 3.73(b)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

  
SignatureAnand R. Baichwal

Printed or Typed Name

8/14/06  
Date(203) 796-3732

Telephone Number

Sr. Vice President Licensing & CSO, Penwest Pharmaceuticals Co.

Title

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